REMARKS

Applicant thanks the Examiner for consideration of the restriction requirement, and acknowledges that Claims 1-12 and 19-24 are currently pending. In the Office Action mailed June 22, 2005, the Examiner has raised several issues, which are set forth by number in the order they are addressed herein:

1) Specification is objected to for failure to remedy sequence identifier omissions;
2) Claims 1-12 and 19-24 stand rejected under 35 U.S.C. § 112 first paragraph, for allegedly lacking enablement;
3) Claims 1, 6, 8, 10 and 19-24 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,093,809 to Cech (Cech);
4) Claims 1-12 and 19-24 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement; and
5) Claims 1, 6-12 and 19-24 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by WO 00/25813 of Nadler et al. (Nadler).

Applicant has amended Claims 19, 21, 22 and 24, canceled Claims 1-12, 20 and 23, and entered new Claims 25-35, in order to further the prosecution of the present application and Applicant's business interests, yet without acquiescing to the Examiner's arguments. Applicant reserves the right to prosecute the original, similar, or broader claims in one or more future application(s). The amendments do not introduce new matter and do not narrow the scope of any of the claims within the meaning of *Festo*.[1]

In particular, Applicant has amended Claim 19 to recite "comprising: at least one **HLA-A2.1-restricted, human** telomerase reverse transcriptase (TRT) peptide from **seven to fifteen amino acid residues in length**." In addition, Applicant has amended Claims 21 and 22 to recite that said human TRT peptide "**consists of**" a peptide having a sequence set forth as SEQ ID NO:1 and SEQ ID NO:2, respectively. Support for these amendments is found for instance in the text of original Claims 6 and 7, in Examples 10 and 11, and in Figure 5, which depicts numerous human TRT peptides possessing the peptide binding motif of HLA-A2.1. Furthermore, Applicant has amended Claim 24 and entered new Claim 27, which now recite

[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

"comprising a helper peptide consisting of a peptide with a sequence set forth as **SEQ ID NO:4**." Furthermore, new Claim 25 recites "wherein said helper peptide is **not conjugated** to said TRT peptide." Support for these claims is found for instance in the footnote to Table II, which recites that in "group 2 and 4 the hTRT peptide was administered together with 140 μg of the helper peptide." Lastly, new Claims 26-35 are directed to compositions comprising "at least one **human telomerase reverse transcriptase (TRT) peptide from seven to fifteen amino acid residues in length**, wherein said TRT peptide comprises **a modification to enhance binding to HLA-A2.1**." Support for these claims is found for instance in original Claims 2 and 10-12, as well as in Example 11, including Table VI.

1) The Specification Is Proper

Applicant thanks the Examiner for informing him that the amendments to the Specification in the Preliminary Amendment submitted November 18, 2003, could not be entered. Accordingly, Applicant has included these amendments to the Specification in the instant response, and has utilized the paragraph numbers of the published application to conform to the format of the originally filed application.

2) The Claims Are Enabled

The Examiner has rejected Claims 1-12 and 19-24 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement (Office Action, Sections 6 and 7). In particular, the Examiner states:

> although the specification discusses the activity of precursor cancer patient T cells stimulated with SEQ ID NO:1 or SEQ ID NO:2 in vitro, and demonstrates generation of SEQ ID NO:1 and 2 specific CTL response in HLA-A2.1 transgenic mice there is no teaching or suggestion that either SEQ ID NO:1 or SEQ ID NO:2 is effective for treatment of any tumor in vivo. For the reasons set forth previously and above, in the absence of objective evidence demonstrating that the claimed invention is effective in a mammal with a tumor load, no one of ordinary skill would believe it more likely than not that the invention would function as claimed with a reasonable expectation of success. . . . Further although the newly added claims [19-24] are drawn to HLA-A2 restricted telomerase reverse transcriptase peptides, the claims are not enabled because the Applicant has not

> overcome the rejections set forth in Section 7 of the previous office action (Office Action, pages 6-8).

Applicant respectfully disagrees that the pending claims lack enablement. As detailed above, Applicant has canceled Claims 1-12 (reciting the term "*vaccine*") and has amended Claim 19 to recite at least one "*HLA-A2.1-restricted*" human TRT peptide. Thus, the currently pending claims DO NOT recite "a vaccine for treating tumors of any origin" let alone the term "vaccine." As such, Applicant contends that it is not necessary to provide evidence that the claimed peptides are effective in a mammal with a tumor load (Applicant's interpretation of the Examiner's rejection of Section 6 of the pending Office Action and Section 7 of the previous Office Action), in order to meet the enablement requirement. Furthermore, Applicant believes that limiting the pending claims to compositions comprising at least one HLA-A2.1 restricted human TRT peptide obviates the Examiner's rejection of Section 7 of the pending Office Action and Section 8 of the previous Office Action. For these reasons, and because Applicant has taught that the exemplary human TRT peptides p540, p865 and p572Y effectively induce a CTL responses after in vitro immunization of murine and human peripheral blood mononuclear cells (PBMC) and/or in vivo immunization of HLA-A2.1 transgenic mice, Applicant believes that the enablement rejections of the pending claims should be withdrawn.

3) The Claims Are Not Anticipated By Cech

The Examiner has consulted a medical dictionary to define a peptide as a compound containing two or amino acids, in order to reject Claims 1, 6, 8, 10 and 19-24 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,093,809 to Cech (Office Action, Section 8). The Examiner states:

> US Patent No. 6,093,809 teaches human telomerase reverse transcriptase (see abstract) and specifically teaches . . . immunizing various hosts by injection of the telomerase protein in combination with various adjuvants including keyhole limpet hemocyanin which is a well know carrier protein, having more that two amino acids, which is a helper peptide (col 30, lines 19-31). Further, a review of the '809 specification reveals a telomerase peptide useful for the method taught wherein said peptide comprises SEQ ID NO:1 (see SEQ ID Nos: 217 and 225 of the '809 patent) and reveals a telomerase peptide useful for the method taught wherein said peptide comprises SEQ ID NO:2 (see SEQ ID Nos: 217 and 225 of

> the '809 patent), and thus the reference teaches a telomerase peptide comprising both SEQ ID NO:1 and SEQ ID NO:2 (Office Action, page 10).

As discussed above, Applicant has amended the pending claims to recite a human TRT peptide from "*seven to fifteen residues in length.*" In contrast, SEQ ID Nos: 217 and 225 of Cech are directed to peptides of 1003 and 1132 amino acids, respectively. As the '809 Patent does not teach the peptide length limitation of the pending claims, Applicant respectfully requests that this rejection be withdrawn.

4) The Claims Meet the Written Description Requirement

The Examiner has rejected Claims 1-12 and 19-24 under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement (Office Action, Sections 9-15). In the first place, the Examiner has rejected Claims 1-12 and 24 for the "limitation of a 'helper peptide' in the absence of the modifier, SEQ ID NO:4 [which] has no clear support in the specification and claims as originally filed" (Office Action, page 11). Although Applicant respectfully disagrees, Applicant has amended the claim set as detailed above, to recite a helper peptide consisting of a peptide with a sequence set forth as *"SEQ ID NO:4."*

In the second place, the Examiner has rejected Claims 21-23 for the "limitation of a peptide comprising" (Office Action, pages 12 and 16). Similarly, in the third place, the Examiner has rejected Claim 23 for the "limitation of a composition comprising 'a first peptide...and a second peptide'" (Office Action, page 12). Although, Applicant respectfully disagrees, Applicant has amended Claims 21 and 22 to recite *"consisting"* in place of "comprising," and has canceled Claim 23, as discussed above.

In the fourth place, the Examiner has rejected Claims 1-5, 8-12, 19, 20 and 24, stating that the Specification "only describes a single human telomerase reverse transcriptase peptide and isolated fragments thereof" (Office Action, page 14). Lastly, the Examiner has rejected Claim 8 for the limitation "wherein the peptide is effective alone" (Office Action, page 17). Although Applicant respectfully disagrees, Applicant has canceled Claim 8 and has amended the claim set as detailed above to recite *"a human telomerase reverse transcriptase peptide."*

Accordingly, Applicant respectfully requests that the written description rejections be withdrawn.

5) The Claims Are Not Anticipated By Nadler

The Examiner has rejected Claims 1, 6-12, and 19-24 under 35 U.S.C. § 102(e) as allegedly anticipated by WO 00/25813 of Nadler (Office Action, Section 16). The Examiner states:

> WO 00/25813 teaches a vaccine comprising at least one human telomerase reverse transcriptase peptide, ... identical to SEQ ID NO:1, as well as vaccines with/including other hTERT peptides ... 100% identical to the instantly claimed SEQ ID NO:2 (Office Action, page 18).

Applicant asserts that Nadler is not prior art. Applicant provides the "Zanetti Declaration" attached hereto at Tab 1, as evidence that Applicant conceived of the invention prior to the October 29, 1998 priority date of the Nadler PCT application. In addition, the Zanetti Declaration provides evidence that Applicant reduced the invention to practice in the United States before the October 29, 1999 filing date of the Nadler PCT application. As shown in Exhibits 2 and 4-6 referred to in the Zanetti Declaration, compositions comprising an HLA-A2.1-restricted human telomerase reverse transcriptase peptide were used for in vitro immunization of murine and human PBMC to induce cytotoxic T lymphocyte responses. Specifically, compositions comprising an HLA-A2.1-restricted human TRT peptide (p540 corresponding to SEQ ID NO:1, and p865 corresponding to SEQ ID NO:2) were effective in inducing a CTL response against HLA-A2 targets pulsed with p540 and p865. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant believes the amendments and arguments set forth above traverse the Examiner's rejections and therefore request that these grounds for rejection be withdrawn. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect before the mailing of a further Office Action.

Dated: November 22, 2005

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